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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,510	02/20/2004	Ronald Vogels	2578-3982.3US	2693

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,510	VOGELS ET AL.	
	Examiner	Art Unit	
	Q. Janice Li, M.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 are pending and under current examination.

Specification

The specification contains sequence disclosures (e.g. page 6, paragraph 0013) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) but are not present in the Sequence Listing and/or identified in the specification by sequence identifier numbers. Applicant must provide sequence identifiers, in the case that these sequences are not included in the original sequence submission, a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). Further, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible sequence noncompliance. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. A full response to this Office Action must include a complete response to the requirement for a Sequence Listing.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejection

Claim 6 is objected to. It is suggested to replace "in vitro" with "isolated".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are vague and indefinite because of the claim recitation "fibroblast-like or macrophage-like cells". The specification fails to define the term besides giving an example of "synoviocyte", which is not a recognized term in standard English Dictionary or Stedman's Medical Dictionary, thus, it is unclear what type of cells the claims embrace, and the metes and bounds of the claims are unclear. For example, it is unclear whether the terms "fibroblast-like or macrophage-like cells" encompass

macrophages, dendritic cells, stromal cells, and fibroblast cells. For the sake of a compact prosecution, the terms have been interpreted as encompass fibroblast or macrophage.

Claim 6 is vague and indefinite because of claim recitation, "fibroblast-like or macrophage-like cell having been provided with a nucleic acid of interest". Since "provided" may encompass simply place recombinant virus in contact with cells, and does not require the recombinant vector actually transfect said cells, thus, it is unclear whether the claim encompass untransfected fibroblast-like cells, and the metes and bounds of the claims are uncertain.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other

descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement;* Federal Register/ Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 1 recites "fibroblast-like or macrophage-like cells", although macrophage and fibroblast cells are well-known in the art, the characteristics of fibroblast-like or macrophage-like cells are not as well-defined, and the specification does not define the term, the only description regarding the term is limited to synovial cells, which by itself, embrace endothelial, epithelial, fibroblast, and perhaps lymphocytes as indicated in the teachings of *Shang et al* (J Immunol 1998;160:467-74, IDS) and *Lazarovits et al* (J Immunol 1993;151:6482-9, IDS). The specification fails to teach whether these cells that may potentially encompassed by the claims have the same surface receptor(s) compared to synovial cells, that is necessary for the tropism of the recombinant adenoviral vector recited in the claims. Therefore, the specification fails to provide adequate description for the broadly claimed subject matter in terms of distinguishing identifying characteristics necessary for tissue tropism, and fails to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

An adequate written description for a broad term such as "fibroblast-like or macrophage-like cells" requires more than a mere statement that it is part of the invention; what is required is a description of the type of cells encompassed by the

terms and their surface receptors that may be recognized by different adenoviral serotypes since the terms do not appear to be a generally accepted term in the art. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. With respect to the method claims, adequate description of the methods first requires an adequate description of the materials, i.e. specific chemical and physical properties of a chemical, or the type of art-recognized cells, which provide the means for practicing the invention. The court has made it very clear "CONCEPTION OF CHEMICAL COMPOUND REQUIRES THAT INVENTOR BE ABLE TO DEFINE COMPOUND SO AS TO DISTINGUISH IT FROM OTHER MATERIALS, AND TO DESCRIBE HOW TO OBTAIN IT, RATHER THAN SIMPLY DEFINING IT SOLELY BY ITS PRINCIPAL BIOLOGICAL ACTIVITY". *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delivering a nucleic acid of interest specifically or preferably to fibroblast-like or macrophage-like cells associated with synovial cavity

using the recombinant adenoviral vector as recited in the claims, does not reasonably provide enablement for delivering a nucleic acid of interest specifically or preferably to fibroblast-like or macrophage-like cells other than those associated with the synovial cavity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided.

The claims embrace various fibroblast-like or macrophage-like cells having a receptor that could be recognized by the recombinant adenoviral vector recited in the claim (structural basis for tissue tropism of the recited recombinant adenoviral vectors). However, as indicated *supra* in the written description section, the specification fails to provide an adequate description for the broad class of cells encompassed by the claims, and fails to teach the likelihood of the genus of cells to have the same receptor(s) so that the recited groups of recombinant vector could selectively target the genus of fibroblast-like or macrophage-like cells. Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus,

the synovial fibroblast alone is insufficient to describe the genus. Accordingly, the specification fails to support the full scope of the claims.

Further, the specification fails to teach whether the recited recombinant adenoviral vectors would target the genus fibroblast-like and macrophage-like cells other than synovial cells. In fact, the prior art of record teaches that two strains of Ad11 isolated from two different patients differ in their binding ability to epithelial cells of various origins (*Mei et al*, Virol 1998;240:254-66, IDS). Thus, determination of the target effects of a particular fiber protein modification is not predictable until they are actually made and used, hence resulting in a trial and error situation.

Therefore, in view of the limited guidance, the lack of predictability of the art, and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by *D'andrea et al* (Biochem J. 1998;329:681-7).

The claim as written encompasses any unmodified or modified synovial cells. *D'andrea et al* teach cultivated synovial cells and thus anticipate instant claims.

Claims 1-6 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/305,435 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Instantly claimed invention is the genus to claims of the cited application, and thus claims of the cited application anticipates instant claims.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claims 1-6 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The copending Application No. 10/305,435 anticipate instant claims but has a different inventive entity. It is unclear who is the real inventor.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,869,936. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims encompass claims of the cited patent.

The instant claims differ from claims of the cited patent in that it is limited to an in vitro process and isolated cells modified by the claimed process. However, such are fully disclosed in the cited patent.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Accordingly, the inventions as claimed are obvious variants, and co-extensive. The claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25 and 26 of copending Application No. 10/305,435. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim encompasses claims of cited application.

Claims of instant and co-pending application are each drawn to fibroblast-like cells transfected with a recombinant adenoviral serotype 5 having modified fiber protein from a second adenoviral serotype selected from the group consisting of Adv serotype 11, 16, 35, and 51; and encoding a gene of interest. Accordingly, the inventions as claimed are obvious variants, and co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Dave T. Nguyen** can be reached on 571-272-0731. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of formal matters can be directed to the patent analyst, **William Phillips**, whose telephone number is (571) 272-0548.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is **(866) 217-9197**. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

Q. JANICE LI, M.D.
PRIMARY EXAMINER

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QJL
April 17, 2006